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10/798,097	03/11/2004	Fredrik Nilsson	12578/46202	6060

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EXAMINER
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STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/798,097

Applicant(s)

NILSSON, FREDRIK

Examiner

Amber D. Steele

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37, 40-43, 45-46, and 48-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37, 40-43, 45-46, and 48-49 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Notice to Comply.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 38-39, 44, and 47 were cancelled.
- Claims 1-37, 40-43, 45-46, and 48-49 are currently pending.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 30-33 and 36 are drawn to an array, classified in class 436, subclass 518.
  - II. Claims 45-46 are drawn to a data carrier, classified in class 702, subclass 186, for example.
  - III. Claim 37 is drawn to an apparatus, classified in class 435, subclass 283.1.
  - IV. Claims 40-41 and 43 are drawn to a library of binding molecules, classified in class 436, subclass 536, for example.
  - V. Claims 1-27 are drawn to a method for analyzing a heterogeneous sample of proteins or peptides, classified in class 530, subclass 344, for example.
  - VI. Claims 28-29 are drawn to a method of identifying disease-related proteins, classified in class 530, subclass 412, for example.
  - VII. Claims 34-35 are drawn to a method of making an array, classified in class 435, subclass 4+.
  - VIII. Claim 42 is drawn to a method of making a library of binding molecules comprising combining a selector peptide and binding molecules and identifying the binding molecules, classified in class 435, subclass 7.1.

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- IX. Claim 49 is drawn to a method of making a library comprising providing a selector peptide and binding molecules, combining a selector peptide and the binding molecules, identifying the binding molecules that bind a selector peptide, immobilizing the binding molecules on an array, providing a sample of heterogeneous proteins, and separating and characterizing the proteins, classified in class 435, subclass 7.8.
- X. Claim 48 is drawn to a method of administering a pharmaceutical agent specific to a diseased individual, classified in class 424, subclass 130.1, for example.

3. The inventions are independent and/or distinct, each from the other because of the following reasons:

A. Inventions I-IV are drawn to independent and/or patentably distinct products since these products are structurally distinct, possess different physiochemical properties, have different functions and/or uses, and/or require different processing steps. Therefore, Groups I-IV have different issues regarding patentability and enablement. Additionally, Groups I-IV represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group I would not necessarily anticipate or render obvious Groups II-IV and *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups I-IV have a separate status in the art as shown by the different classification (please refer to section 2 above).

B. Groups V-X represent separate and patentably distinct inventions. Groups V-X are drawn to different methods that are directed to different purposes, recite different method steps, and/or use different materials. Therefore, Groups V-X have different issues regarding patentability and enablement. Additionally, Groups V-X represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group V would not necessarily anticipate or render obvious Groups VI-X and *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups V-X have a separate status in the art as shown by the different classification (please refer to section 2 above).

C. Inventions I and V-VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using the product (e.g. separating and identifying a heterogeneous sample of polynucleotides which may relate to a disease). In addition, Groups V-VI have been shown to be separate and patentably distinct inventions (please refer to section 3B above).

D. Inventions V-VI and III are related as processes and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process.

(MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process (e.g. separating a heterogeneous sample of polynucleotides which may relate to a disease). In addition, Groups V-VI have been shown to be separate and patentably distinct inventions (please refer to section 3B above).

E. Inventions VII and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process (e.g. isolating different antibodies with different binding specificities from different mammals and immobilizing the antibodies at a defined and discrete location on an array).

F. Inventions VIII-IX and IV are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process (e.g. site directed mutagenesis and screening for binding). In addition, Groups VIII-IX have been shown to be separate and patentably distinct inventions (please refer to section 3B above).

G. Inventions I-IV and VIII-X are drawn to independent and/or patentably distinct products and/or methods since these products and/or methods are structurally distinct, possess different physiochemical properties, have different functions and/or uses, and/or require different processing steps, are directed to different purposes, recite different method steps, and/or use different materials. Therefore, Groups I-IV and VIII-X have different issues regarding patentability and enablement. Additionally, Groups I-IV and VIII-X represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group I would not necessarily anticipate or render obvious Groups II-IV or VIII-X and *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups I-IV and VIII-X have a separate status in the art as shown by the different classification (please refer to section 2 above). Moreover, Groups I-IV have been shown to be independent and/or patentable distinct products (please refer to section 3A above) and Groups VIII-X have been shown to be independent and/or patentable distinct products (please refer to section 3B above).

H. Inventions II-IV and VII are drawn to independent and/or patentably distinct products and/or methods since these products and/or methods are structurally distinct, possess different physiochemical properties, have different functions and/or uses, and/or require different processing steps, are directed to different purposes, recite different method steps, and/or use different materials. Therefore, Groups II-IV and VII have different issues regarding patentability and enablement. Additionally, Groups II-IV and VII represent patentably distinct subject matter which merits separate and

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burdensome searches. Art anticipating or rendering obvious Group II would not necessarily anticipate or render obvious Groups III-IV or VII and *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups II-IV and VII have a separate status in the art as shown by the different classification (please refer to section 2 above). Moreover, Groups II-IV have been shown to be independent and/or patentable distinct products (please refer to section 3A above).

I. Inventions II, IV, and V-VI are drawn to independent and/or patentably distinct products and/or methods since these products and/or methods are structurally distinct, possess different physiochemical properties, have different functions and/or uses, and/or require different processing steps, are directed to different purposes, recite different method steps, and/or use different materials. Therefore, Groups II, IV, and V-VI have different issues regarding patentability and enablement. Additionally, Groups II, IV, and V-VI represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group II would not necessarily anticipate or render obvious Groups IV or V-VI and *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups II, IV, and V-VI have a separate status in the art as shown by the different classification (please refer to section 2 above). Moreover, Groups II and IV have been shown to be independent and/or patentable distinct products (please refer to section 3A above) and Groups V-VI have been shown to be independent and/or patentably distinct methods (please refer to section 3B above).

4. Because these inventions are distinct for the reasons given above and:



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- a. have acquired a separate status in the art as shown by their different classification (please refer to paragraph 1), and/or
- b. divergent subject matter which would require different bibliographic and/or classification searches; and/or
- c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Species Election (Burdensome Search)***

5. This application contains claims directed to the following patentably distinct Markush groups and/or species of the claimed inventions for Groups I-X. Election is required as follows.

6. If applicant elects the inventions of **Group I**, the applicant is required to elect from the following Markush and/or species.

A. species of “binding molecules” [e.g. scFv (please refer to claim 33 and Specification: page 27, lines 13-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

B. species of “number of binding molecules” [e.g. 10 (please refer to claim 32)]

Applicant must elect, for the purposes of search, a **single, specific species** of “number of binding molecules”.

C. species of “motif” [e.g. C-terminal of sample peptides (please refer to Specification: page 27, lines 14-15)]

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Applicant must elect, for the purposes of search, a **single, specific species** of “motif”. In addition, applicant must indicate the length of the motif. Furthermore, applicant must indicate if any variable amino acids are included in the motif and, if so, indicate the number of variable amino acids.

D. species of “capture” [e.g. 100% (please refer to claim 31)]

Applicant must elect, for the purposes of search, a **single, specific species** of “capture”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

7. If applicant elects the invention of **Group II**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “data carrier” [e.g. computer (please refer to Specification: page 25, lines 2-3)]

Applicant must elect, for the purposes of search, a **single, specific species** of “data carrier”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

8. If applicant elects the invention of **Group III**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “data carrier” [e.g. computer (please refer to Specification: page 25, lines 2-3)]

Applicant must elect, for the purposes of search, a **single, specific species** of “data carrier”.

B. species of “array” [e.g. scFv-(His)<sub>6</sub> spotted on Ni-chelate-modified glass slides (please refer to Specification: page 32, lines 12-25)]

Applicant must elect, for the purposes of search, a **single, specific species** of “array”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily

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anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

9. If applicant elects the invention of **Group IV**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “binding molecules” [e.g. scFv (please refer to claim 41 and Specification: page 27, lines 13-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

B. species of “number of binding molecules” [e.g. 10 (please refer to claims 40 and 43)]

Applicant must elect, for the purposes of search, a **single, specific species** of “number of binding molecules”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

10. If applicant elects the invention of **Group V**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “binding molecules” [e.g. scFv (please refer to claims 18-20 and Specification: page 27, lines 13-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

B. species of “number of binding molecules” [e.g. 10 (please refer to claim 17)]

Applicant must elect, for the purposes of search, a **single, specific species** of “number of binding molecules”.

C. species of “motif” [e.g. C-terminal of sample peptides (please refer to Specification: page 27, lines 14-15)]

Applicant must elect, for the purposes of search, a **single, specific species** of “motif”. In addition, applicant must indicate the length of the motif. Furthermore, applicant must indicate if any variable amino acids are included in the motif and, if so, indicate the number of variable amino acids.

D. species of “capture” [e.g. 100% (please refer to claims 14-16)]

Applicant must elect, for the purposes of search, a **single, specific species** of “capture”.

E. species of “heterogeneous sample” [e.g. fragmented plasma proteins (please refer to claims 1-2 and Specification: page 31, lines 10-12)]

Applicant must elect, for the purposes of search, a **single, specific species** of “heterogeneous sample”.

F. species of “fragmenting” [e.g. trypsin (please refer to claims 4-6)]

Applicant must elect, for the purposes of search, a **single, specific species** of “fragmenting”.

G. species of “characterizing” [e.g. desorption mass spectrometry (please refer to claim 24 and Specification: page 23, lines 8-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “characterizing”.

H. species of “identifying” [e.g. collision induced mass spectrometry (please refer to claim 24 and Specification: page 23, lines 16-20)]

Applicant must elect, for the purposes of search, a **single, specific species** of “identifying”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

11. If applicant elects the invention of **Group VI**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “binding molecules” [e.g. scFv (please refer to Specification: page 27, lines 13-14)]

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Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

B. species of “motif” [e.g. C-terminal of sample peptides (please refer to

Specification: page 27, lines 14-15)]

Applicant must elect, for the purposes of search, a **single, specific species** of “motif”. In addition, applicant must indicate the length of the motif. Furthermore, applicant must indicate if any variable amino acids are included in the motif and, if so, indicate the number of variable amino acids.

C. species of “sample” [e.g. fragmented plasma proteins (please refer to

Specification: page 31, lines 10-12)]

Applicant must elect, for the purposes of search, a **single, specific species** of “heterogeneous sample”.

D. species of “fragmenting” [e.g. trypsin (please refer to Specification: page 31, lines 10-12)]

Applicant must elect, for the purposes of search, a **single, specific species** of “fragmenting”.

E. species of “characterizing” [e.g. desorption mass spectrometry (please refer to

Specification: page 23, lines 8-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “characterizing”.

F. species of “identifying” [e.g. collision induced mass spectrometry (please refer to

Specification: page 23, lines 16-20)]

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Applicant must elect, for the purposes of search, a **single, specific species** of “identifying”.

G. species of “disease” [e.g. cancer (please refer to Specification: page 26, line 1)]

Applicant must elect, for the purposes of search, a **single, specific species** of “disease”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

12. If applicant elects the invention of **Group VII**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “binding molecules” [e.g. scFv (please refer to claim 35 and Specification: page 27, lines 13-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

B. species of “motif” [e.g. C-terminal of sample peptides (please refer to Specification: page 27, lines 14-15)]

Applicant must elect, for the purposes of search, a **single, specific species** of “motif”. In addition, applicant must indicate the length of the motif. Furthermore, applicant must



indicate if any variable amino acids are included in the motif and, if so, indicate the number of variable amino acids.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

13. If applicant elects the invention of **Group VIII**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “binding molecules” [e.g. scFv (please refer to claim 35 and Specification: page 27, lines 13-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

B. species of “motif” [e.g. C-terminal of sample peptides (please refer to Specification: page 27, lines 14-15)]

Applicant must elect, for the purposes of search, a **single, specific species** of “motif”. In addition, applicant must indicate the length of the motif. Furthermore, applicant must indicate if any variable amino acids are included in the motif and, if so, indicate the number of variable amino acids.

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C. species of “identifying” [e.g. collision induced mass spectrometry (please refer to Specification: page 23, lines 16-20)]

Applicant must elect, for the purposes of search, a **single, specific species** of “identifying”.

D. species of “selector peptide” [e.g. fragmented plasma proteins (please refer to Specification: page 31, lines 10-12)]

Applicant must elect, for the purposes of search, a **single, specific species** of “selector peptide”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

14. If applicant elects the invention of **Group IX**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “selector peptide” [e.g. synthetic peptides with lysine and biotin (please refer to Specification: page 34, lines 10-15)]

Applicant must elect, for the purposes of search, a **single, specific species** of “synthetic peptides”.

B. species of “binding molecules” [e.g. scFv (please refer to Specification: page 27, lines 13-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “binding molecules”.

C. species of “motif” [e.g. C-terminal of sample peptides (please refer to Specification: page 27, lines 14-15)]

Applicant must elect, for the purposes of search, a **single, specific species** of “motif”. In addition, applicant must indicate the length of the motif. Furthermore, applicant must indicate if any variable amino acids are included in the motif and, if so, indicate the number of variable amino acids.

D. species of “heterogeneous sample” [e.g. fragmented plasma proteins (please refer to claims 1-2 and Specification: page 31, lines 10-12)]

Applicant must elect, for the purposes of search, a **single, specific species** of “heterogeneous sample”.

E. species of “characterizing” [e.g. desorption mass spectrometry (please refer to claim 24 and Specification: page 23, lines 8-14)]

Applicant must elect, for the purposes of search, a **single, specific species** of “characterizing”.

F. species of “identifying” [e.g. collision induced mass spectrometry (please refer to claim 24 and Specification: page 23, lines 16-20)]

Applicant must elect, for the purposes of search, a **single, specific species** of “identifying”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

15. If applicant elects the invention of **Group II**, the applicant is required to elect from the following Markush groups and/or species.

A. species of “pharmaceutical agent” [e.g. scFv (please refer to Specification: page 38, line 17)]

Applicant must elect, for the purposes of search, a **single, specific species** of “pharmaceutical agent”.

B. species of “disease” [e.g. cancer (please refer to Specification: page 26, line 1)]

Applicant must elect, for the purposes of search, a **single, specific species** of “disease”.

It would necessarily be unduly burdensome to search each of the above Markush members and/or species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily

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anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

18. Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR

1.143). Because the above restriction/election requirement is complex, a telephone call to applicant to request an oral election was not made. See MPEP § 812.01.

20. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may

result in a loss of the right to a rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Future Correspondences***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS

August 23, 2005



**ANDREW WANG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600**

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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20050823

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**


**Commissioner for Patents**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply with requirements for patent Applications containing nucleotide sequence and/or amino acid sequence disclosures.

Any inquiry concerning this communication should be directed to Amber D. Steele, Art Unit 1639, whose telephone number is 571-272-5538.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 571-272-1600.

Applicant is given ONE MONTH from the date of this letter within which to comply with the Sequence Rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In NO case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.



**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**



<b>Notice to Comply</b>	<b>Application No.</b> 10798097	<b>Applicant(s)</b> NILSSON, FREDRIK	
	<b>Examiner</b> Amber D.. Steele	<b>Art Unit</b> 1639	

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Specification: page 28, lines 5-6; page 35, Table 2; page 36, line 1

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510

For CRF Submission Help, call (571) 272-2501/2583.

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